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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,558	07/17/2001	Stefan Dietmar Anker	ICI 102	9145

7590

11/29/2002

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 11/29/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

# Office Action Summary

Application No.  
09/807,558

Applicant(s)

Anker

Examiner

Fozia Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31, 35-41, 46, and 47 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-31, 35-41, 46, and 47 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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*Election/Restriction*

1. Claims 32-34 and 42-45 have been canceled and new claims 46-47 have been added in the preliminary amendment filed on 17 July 2001 in Paper No:5. Thus claims 1-31, 35-41 and 46-47 are pending.
2. This application is a 371 of PCT/GB99/03302. For applications filed under 371, PCT rules for lack of unity apply.
3. This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept. Under PCT Rule 13.1 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required:

Applicants are advised that claims 1-2, 36, 39 and 41 are improper Markush claims because the multiple products used in the methods of claims 1-2, 36, 39 and 41, an aldosterone inhibitor, a chymase inhibitor, a cathepsin inhibitor, a receptor blocker, an opiate inhibitor, an endothelin receptor antagonist, a xanthine oxidase inhibitor and erythropoietin, do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. Because each of these products is different, independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art compounds.

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1. Claims 1-4, 30-31, 36, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a compound which inhibits the effect of aldosterone.
2. Claims 1-2, 5-6, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a chymase inhibitor.
3. Claims 1-2, 7-8, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a cathepsin inhibitor.
4. Claims 1-2, 9-10, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a receptor blocker.
5. Claims 1-2, 11-13, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an imidazoline receptor antagonist.
6. Claims 1-2, 14, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of clonidine.
7. Claims 1-2, 15-16, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a peripherally acting receptor antagonist.

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8. Claims 1-2, 17-18, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a ganglion blocking agent.
9. Claims 1-2, 19-21, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an opiate.
10. Claims 1-2, 19, 22, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of scopolamine.
11. Claims 1-2, 23-24, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an endothelin receptor antagonist.
12. Claims 1-2, 25-26, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an xanthine oxidase inhibitor.
13. Claims 1-2, 27, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of erythropoietin.
14. Claims 28, 37, 46-47, drawn to a method of treating weight loss due to underlying disease, by electrically stimulating the patient's muscles.

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15. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of an agent which reduces sympathetic nervous activity.
16. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of aldosterone antagonist.
17. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a chymase inhibitor.
18. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a cathepsin inhibitor.
19. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of an imidazoline antagonist.
20. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a ganglion blocking agent.
21. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of opiate.
22. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a digitalis alkoid.
23. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of scopolamine.

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24. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of growth hormone.
25. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of insulin like growth factor
26. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of an endothelin antagonist.
27. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a TNF antagonist.
28. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of a xanthine oxidase inhibitor.
29. Claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of erythropoietin.
30. Claim 40, drawn to a method of enhancing exercise performance in a healthy patient, by electrically stimulating the patient's muscles.

The inventions listed as Groups 1-30 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The method of treating weight loss due to an underlying disease, by administering to the patient an effective amount a compound which improves cardiovascular reflex status is not itself an advance over the prior art, because Zhenwen et al. (Zhonghua Xinxeguanbing Zazhi, 1996), describe a method of treating chronic congestive heart failure by

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administering the anti-aldosterone agents, captopril alone or in combination with spironolactone, and showed that there was a reduction in excess weight loss. Because neither the process nor product are novel and, therefore, do share a special technical feature, the groups do not relate to a single inventive concept.

Claims 29 and 46 recite several disease conditions which can result in weight loss.

The species recited in claims 29 and 46 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: These species of diseases are different with different symptoms and causes and can be treated with different products.

Applicant is required, in reply to this action, to elect a method of treatment for a single disease to which the claims 29 and 46 shall be restricted. The reply must also identify the claims readable on the elected disease, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

***Advisory Information***

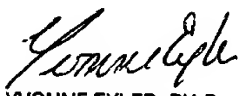
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
19 November 2002

  
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